14 CV 2357

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., and BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM,

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC.

Defendant.

Civil Action No. _____

COMPLAINT

Plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., and Board of Regents of the University of Texas System (collectively, "Plaintiffs"), for their Complaint against Defendant Teva Pharmaceuticals USA, Inc. ("Teva" or "Defendant"), aver as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, for infringement of U.S. Patent No. 6,488,963 (the "'963 patent").

2. By this action, Plaintiffs seek to prevent Teva from attempting to litigate claims to a patent to which Teva had previously filed a "Paragraph III" certification under 21

U.S.C. § 355(j)(2)(A)(vii)(III). Teva could have but did not pursue these patent claims in prior litigation between the parties in cases that have now reached final judgment.

THE PARTIES: PLAINTIFFS

3. Plaintiff Purdue Pharma L.P. ("Purdue Pharma") is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901-3431. Purdue Pharma is an exclusive sublicensee of the '963 patent. Purdue Pharma is also the holder of approved New Drug Application ("NDA") No. 022272 for the controlled-release oxycodone pain-relief medication OxyContin®, and is involved in the sales of OxyContin® in the United States.

4. Plaintiff The P.F. Laboratories, Inc. ("P.F. Labs") is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at 700 Union Boulevard, Totowa, NJ 07512. P.F. Labs is involved in the manufacture of controlled-release oxycodone pain-relief medication under the brand name OxyContin®.

5. Plaintiff Purdue Pharmaceuticals L.P. ("Purdue Pharmaceuticals") is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at 4701 Purdue Drive, Wilson, NC 27893. Purdue Pharmaceuticals is involved in the manufacture of controlled-release oxycodone pain-relief medication under the brand name OxyContin®.

6. Plaintiff Board of Regents of The University of Texas System ("University of Texas System") is an agency organized and existing under the laws of the State of Texas, having an address at 201 West 7th Street, Austin, TX 78701. University of Texas System is the owner of the '963 patent identified in paragraph 13 below.

THE PARTIES: DEFENDANT

7. Upon information and belief, Defendant Teva Pharmaceuticals USA, Inc. ("Teva") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, PA 19454.

8. Upon information and belief, Teva is registered as a Pharmacy Establishment in the State of New York by the New York State Department of Education, Office of the Professions. (Registration Nos. 028138, 029801, and 025905). The Registrations have an active status and are valid through September 30, 2015, August 31, 2015, and February 28, 2015, respectively.

9. Upon information and belief, Teva is registered as a Foreign Business Corporation by the New York State Department of State, Division of Corporations and lists Corporate Creations Network Inc., 15 North Mill Street, Nyack, NY 10960 as its registered agent.

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

11. This Court has personal jurisdiction over Teva because, *inter alia*, Teva has purposefully availed itself of the rights and benefits of the laws of this State and this Judicial District. Upon information and belief, Teva does business in this State and this Judicial District, has engaged in continuous and systematic contact with this State and this Judicial District, and derives substantial revenue from things used or consumed in this State and this Judicial District. Upon information and belief, Teva engages in the manufacture and sale of a range of pharmaceutical products within and directed to the United States, this State, and this Judicial

District specifically. Teva did not contest personal jurisdiction in this Judicial District in a series of patent cases concerning United States Patent Nos. 7,674,799 (the "'799 patent"), 7,674,800 (the "'800 patent"), 7,683,072 (the "'072 patent"), 7,776,314 (the "'314 patent"), 8,114,383 (the "'383 patent"), 8,309,060 (the "'060 patent"), and 8,337,888 (the "'888 patent"). These cases were based on the same Abbreviated New Drug Application ("ANDA") No. 202455, described in paragraph 42 below, that Teva submitted to the FDA based on Purdue Pharma's OxyContin® NDA No. 022272. *See Purdue Pharma L.P. et al. v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 11-cv-2037 (SHS) (S.D.N.Y. Mar. 23, 2011); *Purdue Pharma L.P. et al. v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 12-cv-5083 (SHS) (S.D.N.Y. June 26, 2012); *Purdue Pharma L.P. et al. v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 13-cv-4606 (SHS) (S.D.N.Y. July 2, 2013). Further, this Court has personal jurisdiction over Teva because Teva is registered as a Pharmacy Establishment in the State of New York by the New York State Department of Education, Office of the Professions and as a Foreign Business Corporation by the New York State Department of State, Division of Corporations. In addition, upon information and belief, Teva is actively preparing to make the proposed generic copies of OxyContin® that are the subject of ANDA No. 202455, and to use, sell and offer for sale such generic copies in this State and this Judicial District.

12. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

THE PATENT IN SUIT

13. Plaintiff University of Texas System is the lawful owner of all right, title and interest in the '963 patent entitled "HOT-MELT EXTRUDABLE PHARMACEUTICAL FORMULATION," including the right to sue and to recover for past infringement thereof.

Plaintiff University of Texas System granted an exclusive license under the '963 patent to Abbott Laboratories, which, in turn, granted an exclusive sublicense under that patent to Plaintiff Purdue Pharma. Abbott Laboratories subsequently transferred its interest in the '963 patent to AbbVie Inc. The '963 patent is listed in the U.S. Food and Drug Administration's ("FDA") "Orange Book" *(Approved Drug Products With Therapeutic Equivalence Evaluation)* as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '963 patent, attached hereto as Exhibit A, was duly and legally issued on December 3, 2002, naming James W. McGinity and Feng Zhang as the inventors.

THE NOTICE REQUIREMENTS OF THE HATCH-WAXMAN ACT

14. The Hatch-Waxman Act states that "[i]t shall be an act of infringement to submit [an ANDA] for a drug claimed in a patent or the use of which is claimed in a patent." 35 U.S.C. § 271(e)(2)(A).

15. The Hatch-Waxman Act imposes on NDA filers the obligation to list in the Orange Book "any patent which claims the drug [that is the subject of the submitted NDA] ... with respect to which a claim of patent infringement could reasonably be asserted." 21 U.S.C. § 355(b)(1)(G).

16. The Hatch-Waxman Act imposes on ANDA applicants the corresponding statutory obligation to file "a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug." *Id.* § 355(j)(2)(A)(vii).

17. Under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), the ANDA applicant can certify, with respect to each patent listed in the Orange Book, either that (I) no patents are listed in the Orange Book in conjunction with the product (a "Paragraph I certification"); (II) the listed patent has expired (a "Paragraph II certification"); (III) the ANDA applicant is not seeking FDA

approval to market its generic product until after the expiration date of the listed patent (a "Paragraph III certification"); or (IV) the ANDA applicant seeks approval to market its product before the expiration date of the listed patent, because in the applicant's view the patents are invalid, unenforceable, and/or would not be infringed by the use or sale of the proposed generic product (a "Paragraph IV certification"). *See id.*

18. When the ANDA applicant submits a Paragraph IV certification, it is required to provide notice to the patent holder, including with that notice "a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed," including "[f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed," and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 U.S.C. § 355(j)(2)(B)(iv)(II); 21 C.F.R. § 314.52(c)(6).

19. An ANDA applicant filing Paragraph IV certifications must certify that the relevant patent is not infringed or invalid "to the best of his knowledge". 21 U.S.C. § 355(j)(2)(A)(vii).

20. "The Hatch-Waxman Act thus imposes a duty of care on an ANDA certifier." *Yamanouchi Pharm. Co., Ltd. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1347 (Fed. Cir. 2000).

21. The Hatch-Waxman Act instructs that, in a patent-infringement action filed in response to a Paragraph IV certification, "each of the parties shall reasonably cooperate in expediting the action." 21 U.S.C. § 355(j)(5)(B)(iii).

22. FDA regulations state that an ANDA filer "shall amend a submitted certification if, at any time before the effective date of the application, the applicant learns that the submitted certification is no longer accurate." 21 C.F.R. § 314.94(a)(12)(viii)(C).

THE OXYCONTIN® ORANGE BOOK LISTED PATENTS

23. NDA No. 022272 for the controlled-release oxycodone pain-relief medication OxyContin® was approved by the FDA on April 5, 2010.

24. U.S. Patent No. 5,508,042 (the "'042 patent") issued on April 16, 1996, and expired on April 16, 2013.

25. The '963 patent issued on December 3, 2002, and is listed in the Orange Book as having an expiration date of June 24, 2017.

26. The '799 patent issued on March 9, 2010, and is listed in the Orange Book as having an expiration date of March 30, 2025.[1]

27. The '800 patent issued on March 9, 2010, and is listed in the Orange Book as having an expiration date of March 30, 2025.

28. The '072 patent issued on March 23, 2010, and is listed in the Orange Book as having an expiration date of March 30, 2025.

29. On or around April 6, 2010, Purdue Pharma submitted the following five patents for listing in the FDA's Orange Book as covering OxyContin® (NDA No. 022272): the '042, '963, '799, '800, and '072 patents.

30. The '314 patent issued on August 17, 2010, and is listed in the Orange Book as having an expiration date of April 19, 2025.

[1] Certain claims of the '799, '800, '072, '314, and '383 patents were found to be invalid in a January 14, 2014 Opinion. *See In re OxyContin Antitrust Litigation*, 04-md-1603 (SHS), Findings of Fact and Conclusions of Law, D.I. 634.

31. On or around September 14, 2010, Purdue Pharma submitted the '314 patent for listing in the FDA's Orange Book as covering OxyContin® (NDA No. 022272).

32. On or before September 28, 2010, the following six patents were listed in the FDA's Orange Book as covering OxyContin® (NDA No. 022272): the '042, '963, '799, '800, '072, and '314 patents.

33. The '383 patent issued on February 14, 2012, and is listed in the Orange Book as having an expiration date of October 10, 2024.

34. On or around February 14, 2012, Purdue Pharma submitted the '383 patent for listing in the FDA's Orange Book as covering OxyContin® (NDA No. 022272), 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg.

35. On or around June 26, 2012, Purdue Pharma submitted to the FDA an amendment to its listing of the '383 patent in the FDA's Orange Book as covering OxyContin® (NDA No. 022272), 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg.

36. On or before July 15, 2012, the following seven patents were listed in the FDA's Orange Book as covering OxyContin® (NDA No. 022272): the '042, '963, '799, '800, '072, '314, and '383 patents.

37. The '060 patent issued on November 13, 2012, and is listed in the Orange Book as having an expiration date of November 20, 2023.

38. On or around November 14, 2012, Purdue Pharma submitted the '060 patent for listing in the FDA's Orange Book as covering OxyContin® (NDA No. 022272).

39. The '888 patent issued on December 25, 2012, and is listed in the Orange Book as having an expiration date of August 6, 2022.

40. On or around December 26, 2012, Purdue Pharma submitted the '888 patent for listing in the FDA's Orange Book as covering OxyContin® (NDA No. 022272).

41. On or before January 15, 2013, the following nine patents were listed in the FDA's Orange Book as covering OxyContin® (NDA No. 022272): the '042, '963, '799, '800, '072, '314, '383, '060, and '888 patents.

DEFENDANT'S ANDA

42. Upon information and belief, on or before February 9, 2011, Teva filed ANDA No. 202455 with the FDA ("Teva's original ANDA"), under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale or importation of generic oxycodone hydrochloride extended release tablets ("proposed generic copies of OxyContin®") based on the Reference Listed Drug ("RLD") OxyContin®, which is the subject of approved NDA No. 022272, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, upon expiration of the '963 patent, based on Teva's Paragraph III certification with respect to the '963 patent.

43. At the time it was filed, Teva's original ANDA No. 202455 contained a "Paragraph III" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(III) with respect to the '963 patent.

44. At the time it was filed, Teva's original ANDA No. 202455 contained a Paragraph III certification under 21 U.S.C. § 355(j)(2)(A)(vii)(III) with respect to the '042 patent, pursuant to Consent Judgments between, *inter alia*, Teva and Purdue Pharma. *See Purdue Pharma L.P. et al. v. Teva Pharmaceuticals USA, Inc.*, 03-cv-2312 (SHS) (S.D.N.Y. April 3, 2003), Consent Judgment entered on October 16, 2006, D.I. 47; *In re OxyContin®*

Antitrust Litigation, 04-md-1603 (SHS) (S.D.N.Y. April 23, 2004), Consent Judgment entered on October 26, 2009, D.I. 237.

45. At the time it was filed, Teva's original ANDA No. 202455 contained a Paragraph IV certification with respect to the other patents listed in the FDA's Orange Book at the time of initial filing of Teva's ANDA No. 202455, *i.e.*, the '799, '800, '072, and '314 patents.

46. On or before May 14, 2012, Teva made one or more submissions to the FDA to amend its ANDA No. 202455 to contain a Paragraph IV certification for the '383 patent concerning Teva's proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg.

47. On or before May 21, 2013, Teva made one or more submissions to the FDA to amend its ANDA No. 202455 to contain a Paragraph IV certification for the '060 and '888 patents.

48. On or before December 20, 2013, Teva made one or more submissions to the FDA to amend its ANDA No. 202455 to contain a Paragraph IV certification for the '383 patent concerning Teva's proposed generic copies of OxyContin®, 60mg and 80 mg.

49. In each of Teva's submissions to the FDA on or before December 20, 2013, which submissions amended Teva's ANDA No. 202455 to contain Paragraph IV certifications for the '383, '060, and '888 patents, Teva's ANDA No. 202455 maintained its Paragraph III certification with respect to the '963 patent.

50. On information and belief, after the January 22, 2014 entry of final judgment in C.A. 04-md-1603 (SHS), D.I. 637, Teva made a submission to the FDA to amend its ANDA No. 202455 to contain a Paragraph IV alleging that the '963 patent, listed in the FDA's

Orange Book as covering the drug OxyContin®, which is the subject of approved NDA No. 022272, is "invalid, unenforceable, or not infringed . . . by the commercial manufacture, use, or sale of [the proposed generic copies of OxyContin®]."

TEVA'S PRIOR NOTICES TO PURDUE AND THE CORRESPONDING *PURDUE V. TEVA* ACTIONS

51. On or around February 9, 2011, the following six patents were listed in the FDA's Orange Book as covering OxyContin® (NDA No. 022272): the '042, '963, '799, '800, '072, and '314 patents.

52. In a letter dated February 9, 2011, addressed to, *inter alia*, Purdue Pharma and received by Purdue Pharma on or around February 10, 2011, Teva provided notice that its ANDA No. 202455 concerning the proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, contained a Paragraph IV certification alleging that the '799, '800, '072, and '314 patents are "invalid, unenforceable, or not infringed . . . by the commercial manufacture, use, or sale of [the proposed generic copies of OxyContin®]."

53. On or around February 9, 2011, Teva's original ANDA No. 202455 contained a Paragraph III certification with respect to the '963 patent.

54. On or around March 23, 2011, Purdue filed a Complaint against Teva for patent infringement, alleging that Teva's ANDA No. 202455 infringed the '799, '800, '072, and '314 patents. This action was captioned as *Purdue Pharma L.P. et al. v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 11-cv-2037 (SHS) (S.D.N.Y. Mar. 23, 2011) (the "11-cv-2037 action").

55. On or around May 14, 2012, the following seven patents were listed in the FDA's Orange Book as covering OxyContin® (NDA No. 022272): the '042, '963, '799, '800, '072, '314, and '383 patents.

56. Purdue Pharma submitted the '383 patent for listing in the FDA's Orange Book as covering OxyContin® (NDA No. 022272), 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg, on or around February 14, 2012. On May 15, 2012, Purdue Pharma received a letter from Teva dated May 14, 2012, in which Teva provided notice that its ANDA No. 202455 concerning the proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg, contained a Paragraph IV certification alleging that the '383 patent is "invalid, unenforceable, or not infringed . . . by the commercial manufacture, use, or sale of [the proposed generic copies of OxyContin®]."

57. On or around May 14, 2012, Teva's original ANDA No. 202455 contained a Paragraph III certification with respect to the '963 patent.

58. On or around June 26, 2012, Purdue filed a second Complaint against Teva for patent infringement with respect to Teva's ANDA No. 202455, alleging that such ANDA infringed the '383 patent. This action was captioned as *Purdue Pharma L.P. et al. v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 12-cv-5083 (SHS) (S.D.N.Y. June 26, 2012) (the "12-cv-5083 action").

59. The 11-cv-2037 and 12-cv-5083 actions were consolidated for purposes of discovery and trial.

60. On or around May 21, 2013, the following nine patents were listed in the FDA's Orange Book as covering OxyContin® (NDA No. 022272): the '042, '963, '799, '800, '072, '314, '383, '060, and '888 patents.

61. Purdue Pharma submitted the '060 and '888 patents for listing in the FDA's Orange Book as covering OxyContin® (NDA No. 022272) on or around November 14, 2012 and December 26, 2012, respectively. On May 22, 2013, Purdue Pharma received a letter

from Teva dated May 21, 2013, in which Teva provided notice that its ANDA No. 202455 concerning the proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, contained a Paragraph IV certification alleging that the '060 and '888 patents are "invalid, unenforceable, or not infringed . . . by the commercial manufacture, use, or sale of [the proposed generic copies of OxyContin®]."

62. On or around May 21, 2013, Teva's original ANDA No. 202455 contained a Paragraph III certification with respect to the '963 patent.

63. On or around July 2, 2013, Purdue filed a third Complaint against Teva for patent infringement with respect to Teva's ANDA No. 202455, alleging that such ANDA infringed the '060 and '888 patents. This action was captioned as *Purdue Pharma L.P. et al. v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 13-cv-4606 (SHS) (S.D.N.Y. July 2, 2013) (the "13-cv-4606 action").

64. The 13-cv-4606 action was not consolidated with the 11-cv-2037 and 12-cv-5083 actions for purposes of discovery or trial.

65. On or around December 20, 2013, Teva's original ANDA No. 202455 contained a Paragraph III certification with respect to the '963 patent.

66. On January 22, 2014, a final judgment was entered with respect to all of the claims and counterclaims at issue in the 11-cv-2037 and 12-cv-5083 actions. *See* C.A. 04-md-1603 (SHS) (governing the 11-cv-2037 and 12-cv-5083 actions), Clerk's Judgment entered January 22, 2014, D.I. 637.

67. At all times between the date on which Teva filed its original ANDA No. 202455 concerning the proposed generic copies of OxyContin®, until January 22, 2014, Teva's ANDA No. 202455 contained a Paragraph III certification with respect to the '963 patent. *See*

C.A. No. 04-md-1603 (SHS), Joint Pretrial Order entered August 28, 2013, D.I. 572, at 11 n.1 ("Teva has filed a Paragraph III certification with respect to the '963 Reformulation patent"); C.A. No. 11-cv-2037 (SHS), Findings of Fact and Conclusions of Law entered January 14, 2014, D.I. 149, at 79 n.9 ("Purdue's allegations against Teva do not extend to the '963 Patent, because Teva has not submitted a Paragraph IV certification challenging that patent.").

68. Prior to January 22, 2014, Teva had not amended its ANDA No. 202455 to contain a Paragraph IV certification alleging that the '963 patent is "invalid, unenforceable, or not infringed . . . by the commercial manufacture, use, or sale of [the proposed generic copies of OxyContin®]."

69. Prior to January 22, 2014, Teva had not pled or attempted to plead any claim or defense alleging that the '963 patent is invalid, unenforceable, or not infringed by its ANDA No. 202455. *See*, *e.g.*, C.A. No. 11-cv-2037, Teva's Second Amended Answer, Affirmative Defenses and Counterclaims to Complaint, D.I. 75; C.A. No. 12-cv-5083, Teva's Answer, Affirmative Defenses and Counterclaims to Amended Complaint, D.I. 12.

70. Teva represented during the course of the prior *Purdue v. Teva* actions (the 11-cv-2037, 12-cv-5083, and 13-cv-4606 actions) that Teva was not asserting any claim or defense alleging that the '963 patent is invalid, unenforceable, or not infringed by its ANDA No. 202455.

71. In a letter dated February 18, 2014, addressed to, *inter alia*, Purdue Pharma and the University of Texas System and received by Purdue Pharma on or around February 19, 2014, Teva provided notice that its ANDA No. 202455 concerning the proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, contained a Paragraph IV certification alleging that the '963 patent is "invalid, unenforceable, or

not infringed . . . by the commercial manufacture, use, or sale of [the proposed generic copies of OxyContin®]," thereby demonstrating an actual and justiciable controversy.

FIRST CLAIM FOR RELIEF:
PATENT INFRINGEMENT OF THE '963 PATENT

72. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1-71.

73. Teva's submission of an amended ANDA containing a Paragraph IV certification with respect to the '963 patent was an act of infringement of the '963 patent under the United States Patent Laws, 35 U.S.C. § 271(e)(2)(A), with respect to Teva's proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg.

74. Teva's proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, as described in Teva's ANDA No. 202455, are covered by one or more claims of the '963 patent.

75. Teva's commercial manufacture, use, sale, and/or offer for sale of the proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, as described in Teva's ANDA No. 202455, would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '963 patent.

76. Teva has been aware of the existence of the '963 patent since at least February 9, 2011, and has in the prior *Purdue v. Teva* actions (the 11-cv-2037, 12-cv-5083, and 13-cv-4606 actions) elected not to challenge the validity, enforceability, or noninfringement of the '963 patent, and has no reasonable basis for believing that its proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, as described in Teva's ANDA No. 202455, will not infringe the '963 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

77. The acts of infringement by Teva set forth above will cause Plaintiffs Purdue Pharma, P.F. Labs, and Purdue Pharmaceuticals irreparable harm for which they have no adequate remedy at law, and such harm will continue unless Teva is enjoined by this Court.

SECOND CLAIM FOR RELIEF:
DECLARATORY JUDGMENT THAT TEVA IS BARRED FROM RAISING ANY CLAIM OR DEFENSE WITH RESPECT TO THE '963 PATENT

78. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1-77.

79. An actual and justiciable controversy exists within the meaning of 28 U.S.C. §§ 2201 and 2202 between Plaintiffs and Teva regarding Teva's ability to assert claims, defenses, and/or counterclaims alleging that the '963 patent is invalid, unenforceable, or not infringed because (i) Teva has made a submission to the FDA to amend its ANDA to contain a Paragraph IV certification contending that the '963 patent is "invalid, unenforceable, or not infringed . . . by the commercial manufacture, use, or sale of [the proposed generic copies of OxyContin®]"; (ii) Plaintiffs assert that Teva is barred by the doctrine of claim preclusion, from asserting those contentions; (iii) Plaintiffs assert that Teva is barred by the doctrine of judicial estoppel from asserting those contentions; and (iv) Plaintiffs assert that Teva is barred by all other applicable legal and/or equitable doctrines from asserting those contentions.

80. On information and belief, absent a declaratory judgment that Teva may not assert claims, defenses, and/or counterclaims alleging that the '963 patent is "invalid, unenforceable, or not infringed . . . by the commercial manufacture, use, or sale of [the proposed generic copies of OxyContin®]," Teva will continue to wrongfully assert such contentions, and thereby cause irreparable harm and damage to Plaintiffs.

81. Upon information and belief, if and when the FDA grants tentative approval of Teva's ANDA, Teva will undertake substantial activities directed toward engaging in infringement, contributory infringement, and active inducement of infringement of the '963 patent by making, using, and undertaking substantial preparations for offering to sell Teva's proposed generic copies of OxyContin®, and such acts will constitute infringement, contributory infringement and active inducement of infringement of one or more claims of the '963 patent.

82. Upon information and belief, because Teva has made a submission to the FDA to amend its ANDA to contain a Paragraph IV certification with respect to the '963 patent, Teva will attempt to assert claims, defenses, and/or counterclaims in response to this Complaint alleging that the '963 patent is "invalid, unenforceable, or not infringed . . . by the commercial manufacture, use, or sale of [the proposed generic copies of OxyContin®]."

83. Any attempt by Teva to assert claims, defenses, and/or counterclaims alleging that the '963 patent is "invalid, unenforceable, or not infringed . . . by the commercial manufacture, use, or sale of [the proposed generic copies of OxyContin®]" would be barred by the doctrine of claim preclusion.

84. Any attempt by Teva to assert claims, defenses, and/or counterclaims alleging that the '963 patent is "invalid, unenforceable, or not infringed . . . by the commercial manufacture, use, or sale of [the proposed generic copies of OxyContin®]" would be barred by the doctrine of judicial estoppel.

85. Any attempt by Teva to assert claims, defenses, and/or counterclaims alleging that the '963 patent is "invalid, unenforceable, or not infringed . . . by the commercial manufacture, use, or sale of [the proposed generic copies of OxyContin®]" would be barred by all other applicable legal and/or equitable doctrines.

THIRD CLAIM FOR RELIEF:
INJUNCTION REQUIRING TEVA TO WITHDRAW ITS PARAGRAPH IV CERTIFICATION WITH RESPECT TO THE '963 PATENT

86. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1-85.

87. Upon information and belief, if and when the FDA grants tentative approval of Teva's ANDA, Teva will undertake substantial activities directed toward engaging in infringement, contributory infringement, and active inducement of infringement of the '963 patent by making, using, and undertaking substantial preparations for offering to sell Teva's proposed generic copies of OxyContin®, and such acts will constitute infringement, contributory infringement and active inducement of infringement of one or more claims of the '963 patent.

88. Upon information and belief, Teva has been aware of the existence of the '963 patent since at least February 9, 2011 and, if and when the FDA grants tentative approval of Teva's ANDA, Teva will engage in substantial activities directed toward infringing, contributorily infringing, and actively inducing infringement of the '963 patent. These activities will be in total disregard for Plaintiffs' lawful rights under the '963 patent, thus rendering this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

89. If Teva's purported Paragraph IV certification with respect to the '963 patent is legally effective, any FDA approval of Teva's ANDA could become effective immediately upon passage of the time limits or other requirements of 21 U.S.C. § 355(j)(5)(B)(iii) and 21 U.S.C. § 355(j)(5)(B)(iv), as applicable, prior to expiration of the '963 patent.

90. Teva's purported Paragraph IV certification alleging that the '963 patent is "invalid, unenforceable, or not infringed . . . by the commercial manufacture, use, or sale of [the proposed generic copies of OxyContin®]" is barred by the doctrine of claim preclusion.

91. Teva's purported Paragraph IV certification alleging that the '963 patent is "invalid, unenforceable, or not infringed . . . by the commercial manufacture, use, or sale of [the proposed generic copies of OxyContin®]" is barred by the doctrine of judicial estoppel.

92. Teva's purported Paragraph IV certification alleging that the '963 patent is "invalid, unenforceable, or not infringed . . . by the commercial manufacture, use, or sale of [the proposed generic copies of OxyContin®]" is barred by all other applicable legal and/or equitable doctrines.

93. On information and belief, absent an injunction requiring Teva to withdraw its ANDA amendment containing a Paragraph IV certification with respect to the '963 patent, and resubmit to the FDA an ANDA amendment containing a Paragraph III certification under 21 U.S.C. § 355(j)(2)(A)(vii)(III) with respect to the '963 patent; Teva will continue to wrongfully assert that the '963 patent is "invalid, unenforceable, or not infringed . . . by the commercial manufacture, use, or sale of [the proposed generic copies of OxyContin®]," and thereby cause irreparable harm and damage to Plaintiffs.

WHEREFORE, Plaintiffs pray for judgment:

On Plaintiffs' First Claim for Relief, as Set Forth in the Complaint:

A. Adjudging that Teva has infringed the '963 patent, and that the commercial sale, offer for sale, use, and/or manufacture of the proposed generic copies of OxyContin®, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, as described in ANDA No. 202455 would infringe, induce infringement of, and/or contribute to the infringement of the '963 patent;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 202455, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, under

§ 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), to be a date not earlier than the date of expiration of the '963 patent plus any additional periods of exclusivity;

C. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., Teva, its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product that is the subject of ANDA No. 202455 or any other drug product that infringes the '963 patent;

D. Declaring this an exceptional case and awarding Plaintiffs their attorneys' fees and costs, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

E. Awarding Plaintiffs such other and further relief as this Court may deem just and proper.

On Plaintiffs' Second Claim for Relief, as Set Forth in the Complaint:

F. Declaring that Teva is barred by the doctrine of claim preclusion from asserting any claims, defenses, and/or counterclaims alleging that the '963 patent is "invalid, unenforceable, or not infringed . . . by the commercial manufacture, use, or sale of [the proposed generic copies of OxyContin®]";

G. Declaring that Teva is barred by the doctrine of judicial estoppel from asserting any claims, defenses, and/or counterclaims alleging that the '963 patent is "invalid, unenforceable, or not infringed . . . by the commercial manufacture, use, or sale of [the proposed generic copies of OxyContin®]";

H. Declaring that Teva is barred by all other applicable legal and/or equitable doctrines from asserting any claims, defenses, and/or counterclaims alleging that the '963 patent is "invalid, unenforceable, or not infringed . . . by the commercial manufacture, use, or sale of [the proposed generic copies of OxyContin®]";

I. Enjoining Teva from asserting, in this or any other proceeding, any claims, defenses, and/or counterclaims alleging that the '963 patent is "invalid, unenforceable, or not infringed . . . by the commercial manufacture, use, or sale of [the proposed generic copies of OxyContin®];

J. Declaring this an exceptional case and awarding Plaintiffs their attorneys' fees and costs, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

K. Awarding Plaintiffs such other and further relief as this Court may deem just and proper.

On Plaintiffs' Third Claim for Relief, as Set Forth in the Complaint:

L. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. § 283 and Rule 65, Fed. R. Civ. P., Teva from asserting that its amendment to its ANDA No. 202455 contains a legally effective Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '963 patent; and

M. Ordering that Teva withdraw its ANDA amendment containing a Paragraph IV certification with respect to the '963 patent, and resubmit to the FDA an ANDA amendment containing a Paragraph III certification under 21 U.S.C. § 355(j)(2)(A)(vii)(III) with respect to the '963 patent;

N. Declaring this an exceptional case and awarding Plaintiffs their attorneys' fees and costs, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

O. Awarding Plaintiffs such other and further relief as this Court may deem just and proper.

Date: April 3, 2014

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